

U.S. Appln. S.N. 10/828,351  
AMENDMENT AFTER FINAL REJECTION

PATENT

REMARKS

This Amendment rewrites claim 23. The "substantially constant rate" release feature of claim 23 is supported by page 5, lines 32-34 of the specification and Fig 1. Claims 23-31 are pending.

A Request for Continued Examination (RCE) is attached. Entry of this Amendment is requested.

Examiner Tran is thanked for indicating the allowability of claims 29 and 30. It is believed this Amendment places the entire application in condition for allowance for the reasons which follow.

This Amendment overcomes the 35 U.S.C. § 103(a) rejection of claims 23-28 and 31 over U.S. Patent No. 5,591,453 to Ducheyne et al. in view of International Patent Publication WO 92/20623 to Einarsrud et al. Claim 23 has been amended, in response to the Examiner's comments in the Advisory Action, to specify the biologically active agent is released at a substantially<sup>1</sup> constant rate. This amendment eliminates the Advisory Action's objection to the "controllably releasing" step of the claimed method, and

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<sup>1</sup>"Substantially" is used because the release rate may not be perfectly linear over the entire release period. See Fig. 1.

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patentably distinguishes the claimed method from the diffusion release method of Ducheyne et al..

As discussed more fully in the Request for Reconsideration filed September 1, 2006, the claimed method of administering a biologically active agent into a human or animal body involves the complete dissolution of a silica-xerogel carrier within a desired time period upon contact with body fluid. The silica-xerogel dissolves controllably, and the biologically active agent is released at a substantially constant rate from the silica-xerogel by this silica-xerogel dissolution (Specification, page 5, line 31 to page 6, line 5). The release rate is thus substantially independent of diffusion through the pores of the silica-xerogel. Controlled release of a biologically active agent through biodegradation of the carrier is particularly advantageous when the biologically active agent is a large molecule or even a particulate, and diffusion through the carrier is not an option.

The cited combination of references fails to raise a *prima facie* case of obviousness against the claimed method because the cited references fail to disclose or suggest the "total dissolution of the silica-xerogel carrier" feature of the claimed method. Instead, Ducheyne et al.'s controlled release is achieved primarily

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by diffusion of its bioactive agent through the pores of its silica-based glass rather than by dissolution of its carrier. See, for example, Col. 6, lines 15-17 ("In the case of pure silica glass, the release of the biological molecules from the carrier is effected primarily by diffusion through the pore structure"). Thus, the rate limiting factor in release of the biologically active agent is its diffusion through the pores of the silica-based glass carrier. One of ordinary skill in the art would understand the Ducheyne et al. carrier need not be dissolvable to achieve release of its biologically active agent.

The Advisory Action cites Col. 14, lines 14-37 of Ducheyne et al. to justify maintaining this obviousness rejection. However, the Patent Office paraphrase of the cited passage<sup>2</sup> is incorrect. This passage does not state that there are instances when greater porosity may be desirable to achieve a more rapid degradation of the carrier to facilitate the release of larger molecules. Instead, the cited passage merely suggests greater porosity may achieve a more rapid release of biologically active agent or a more rapid degradation of the carrier. The very next sentence goes on to teach: "Larger pore sizes facilitate the release of larger

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<sup>2</sup>Advisory Action, page 2, lines 18-20.

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molecules through diffusion." (Emphasis supplied). One of ordinary skill in the art, without the benefit of hindsight, would clearly understand that Ducheyne et al. is concerned with release of its biologically active agent by diffusion through the pores of its carrier.

Reconsideration and withdrawal of the obviousness rejection of claims 23-28 and 31 over Ducheyne et al. in view of Einarsrud et al. are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of the rejection of claims 23-28 and 31, and issuance of a Notice of Allowance directed to claims 23-31, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

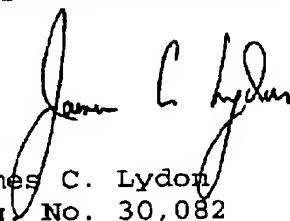
An RCE, and a Petition and fee for a second month Extension of Time are attached. It is not believed any additional fee is required for entry and consideration of this Amendment.

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Nevertheless, the Commissioner is authorized to charge our Deposit  
Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

  
James C. Lydon  
Reg. No. 30,082

Atty. Case No.: **TUR-140-A**  
100 Daingerfield Road  
Suite 100  
Alexandria, Virginia 22314  
Telephone: (703) 838-0445  
Facsimile: (703) 838-0447

Enclosures:

Request for Continued Examination  
Petition for Extension of Time